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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,245	02/18/2004	Jaime Romero	OS 457.002	5228

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,245	ROMERO, JAIME	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,26,30,46,49,50,52-67 and 70-75* is/are pending in the application.

4a) Of the above claim(s) *1-22,26,30,46,49,50 and 52-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's IDS filed on 8 October 2009 and remarks filed on 22 February 2010. Applicant's remarks are persuasive; as such, the amendment filed on 8 October 2009 is deemed to be within the scope of the election made by applicants on 27 December 2006.

* * * * *

Status of the Claims

With the latest amendment, filed on 8 October 2009, claims 1-22, 26, 30, 46, 49, 50, and 52-67 are withdrawn. Claims 23-25, 27-29, 31-45, 47, 48, 51, 68, and 69 are cancelled. Claims 70-75 are rejected.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly presented claims 72 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the concentration range of 20-80% shellac being claimed is not disclosed in the specification. The instant specification defines shellac only as a stabilizer (see filed

specification, [0057]). The highest concentration of stabilizer disclosed in the instant specification is 3% (see filed specification, e.g., [0034], [0043], and [0046]). Examiner respectfully submits that a review of the instant disclosure has not revealed shellac concentration of 20-80%. As such, said limitation is deemed to be new matter.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinner (U.S. Patent No. 6,210,710) in view of Miller (U.S. Application No. 20050008690).

Skinner teaches a timed (sustained) release nutritional supplement (*see* col. 2, lines 8-22). The composition may be comprised of: a stabilizing agent (e.g. ascorbic acid) (see col. 3, line 58); 0-94% of a saccharide (lactose) (see col. 4, line 51); and an active agent such as a mineral or nutritional additive (see col. 3, line 45). The disclosed composition is comprised of a core and coating (*see* col. 5, lines 9-26). It is noted that the instant specification defines shellac only as a stabilizing agent (see filed specification [0057]).

Skinner explains that the disclosed composition is beneficial because it provides flexibility in release profiles that are stable and economical for compressed tablets (*see* col. 1, lines 48-56).

Skinner does not disclose a capsule, talc, Shellac, chondroitin, or glucosamine sulfate.

Miller teaches a capsule formulation (*see* abstract) comprising:

- talc (*see* paragraph 0090);
- Shellac (*see* example 13);
- chondroitin (90%) (*see* paragraph 0377 and example 1); and
- glucosamine sulfate (95%) (*see* paragraph 0377 and example 1).

Miller teaches that the capsule shell may be comprised of hard gelatin (see paragraphs 0009 and 0021), reading on instant claim 70; and a soft gelatin capsule (see paragraphs 0011 and 0021), reading on instant claim 71. The active agent may be in the form of a granulation (see paragraph 0064).

The disclosed concentrations of chondroitin and glucosamine overlap with claims 73 and 75. The claimed range of shellac is very broad, i.e., 20-80%, and can be determined by a person of ordinary skill in the art though routine experimentation or optimization. Particle size may also be determined by routine experimentation or optimization. Applicants have not shown any criticality or unexpected results with the claimed shellac concentration or particle size.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a timed release composition comprising pellets

comprising glucosamine or chondroitin, shellac, and talc in a gelatin capsule, as taught by Skinner in view of Miller. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides flexibility in release profiles that are stable and economical for compressed tablets, as explained by Skinner.

* * * * *

Response to Arguments

Applicant's arguments regarding the 35 USC 103 rejection filed on 8 October 2009 have been fully considered but they are not persuasive. Only arguments relating to pending claims have been addressed; i.e., the arguments directed to claims cancelled in the amendment filed on 8 October 2009 are now moot.

Applicant argues that shellac is an agglutinative (see remarks, page 34). Examiner respectfully disagrees. According to the instant specification, shellac is only defined as a stabilizer (see filed specification [0057]). Shellac is not included in the list of agents disclosed as agglutinatives (see filed specification [0056]).

Applicant argues that the transition phrase is "consisting of" (see remarks, page 33) and that the present invention claims the unexpected result of a functional composition for timed or retarded release of glucosamine or chondroitin using only shellac as the agglutinative layer (see remarks, page 35).

At the outset, as indicated above, the instant specification explicitly defines shellac as a stabilizer and does not include shellac in the list of agents defined as

agglutinatives. Applicant cannot now present a definition of shellac that is inconsistent with what is disclosed in the specification as filed.

Additionally, the transition phrase "consisting of" can only be read as restrictive of the composition generally to multiple pellets and a capsule. The transition phrase “consisting of” has not been used in the claim language reciting the formulation of the pellets (i.e. claims 70(a) and 71(a)). In fact, the "consisting of" language cannot be applied to the formulation of the pellets. To do so would be inconsistent with the written description presented in the disclosure. Throughout the specification, it is disclosed that six components are required for the disclosed formulation: 1) a saccharide, 2) an excipient, 3) a lubricant, 4) an agglutinative; 5) a stabilizer, and 6) a plasticizer. Further, the embodiments of the disclosed composition which are exemplified for the release profile being claimed (examples 1-3) all contain ingredients in addition to those listed in claims 70(a) and 71(a). A restriction of the claimed composition to only glucosamine or chondroitin, shellac, and talc would violate the written description of the filed specification; as such, the formulation of the pellets is deemed to be claimed in open language. It is noted again that the transition phrase “consisting of” has not been used in the claim language reciting the formulation of the pellets (i.e. claims 70(a) and 71(a)).

Applicants argue that Skinner does not disclose shellac and does not teach layered pellets (see remarks, page 37).

Examiner respectfully submits that Skinner discloses a layered core formulation (see obviousness rejection, above). Miller was invoked for the teaching of shellac and multiple pellets (see obviousness rejection, above). It is noted that one cannot show

nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that in the filed declaration, Dr. Dixit declares that percentages for a particular formulation are not attainable by routine experimentation (see remarks, pages 37-39).

As explained in the 35 USC 112 rejection above, the claimed concentration range for shellac is deemed to be new matter. The concentrations of chondroitin and glucosamine are disclosed by Miller (see obviousness rejection, above).

Applicants argue that there is not teaching, suggestion, or motivation to combined the cited references because none of the references teach using shellac alone without plasticizers or binders (see remarks, page 39).

As indicated above, every example and embodiment disclosed by the instant specification which displays the claimed dissolution profile has ingredients in addition to shellac and talc. As such, the pellets being claimed can only be read with open language without violating the written description requirement. Thus the phrase "consisting of" is read as applying to the general composition only; i.e. a composition consisting of multiple pellets and a gelatin capsule.

Applicants argue that Miller does not have any teaching of a formulation to be layered on inert spheres (see remarks, page 40).

Examiner respectfully submits that Skinner was invoked for this teaching (see obviousness rejection, above). Additionally, regarding the process of layering is not

essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

* * * * *

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615